

75 West Center • Provo, Utah 84601-4483 tel 801-345-9800 • fax 801-345-9899 www.pharmanex.com

By Federal Express

November 9, 1999



Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 200 C St. SW Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements

١,

Dear Sir or Madam:

As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex, Inc., 2000 Sierra Point Parkway, Brisbane, California 94005, intends to market a dietary supplement product with the following label statements of nutritional support:

Product identified as Cholestin Bar with the following label statements:

- Promotes healthy cholesterol levels.
- Helps maintain desirable cholesterol levels.
- Helps maintain healthy blood lipid levels.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,

Carsten Smidt

Director of Nutrition Research